**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| **IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION**<br><br>**THIS DOCUMENT RELATES TO:**<br>**All Direct Purchaser Actions** | **Case No. 1:15-cv-07488-CM-RWL** |

**PLAINTIFFS' OPPOSITION TO FOREST'S MOTION *IN LIMINE* NO. 2 SEEKING TO EXCLUDE GENERAL STATISTICAL EVIDENCE OF OUTCOMES IN UNRELATED PHARMACEUTICAL PATENT LITIGATIONS**

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## I.     INTRODUCTION

Plaintiffs request that this Court deny Forest's motion *in limine* No. 2 ("MIL No. 2")
(ECF No. 756), which seeks to exclude evidence of statistical studies on which Plaintiffs' expert
relies. First, Forest's motion fails for procedural reasons.  Notably absent from Forest's
Memorandum In Support of MIL No. 2 ("Defs.' Br.") (ECF No. 757) is any acknowledgement
that Forest previously made the same argument at the *Daubert* stage, and the Court rejected it.
Forest's motion is an untimely motion for reconsideration of the Court's *Daubert* ruling and
should be rejected for that reason alone.

Second, Forest's motion also fails on the merits. Forest's argument that Mr. Johnston's
opinions based on the statistical studies lack "relevance" is premised on the misapprehension that
this is a "patent infringement case."  But as this Court recognized at the *Daubert* stage, this is
"not a patent infringement case."  One of the key issues in this *antitrust* case is how a reasonable
litigant would have viewed its likelihood of success in the Namenda patent litigation.  The
evidence is undisputed that reasonable litigants are aware of, and rely upon, statistical studies of
patentee win rates when evaluating their likelihood of success.  As such, the statistical studies are
highly probative of an important issue in the case, and the only supposedly prejudicial effect is
premised on Forest's misapprehension that this is a patent infringement case.

## II.    ARGUMENT

### A.     This Court Already Resolved the Admissibility of Mr. Johnston's Testimony on Statistical Evidence at the *Daubert* Stage.

Notably absent from Forest's brief is any recognition that this Court already rejected
Forest's challenge to Mr. Johnston's testimony regarding the statistical studies. At the *Daubert*
stage, Forest moved to preclude Mr. Johnston from testifying on various issues *including the
very same statistical studies at issue in MIL No. 2*. Regarding them, Forest wrote:

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> In addition to his improper opinions on the merits of the patent case, Mr. Johnston offers several other reasons why he thinks Forest was likely to lose at trial. . . . [H]e cites *statistical analyses* in support of his blanket claim that patents usually do not hold up in litigation, again implying that the '703 patent was likely to fail. [Johnston Report] *¶¶ 87-109*. . . . All of these opinions are impermissible because *they seek to undermine the statutory presumption of patent validity*, which indisputably applied to the '703 patent, and which could be overturned only by clear and convincing evidence.

ECF No. 644 at 10 (emphasis added).  After reviewing the *very same* paragraphs of Mr. Johnston's report that Forest challenges here (*i.e.*, ¶¶ 87-109), this Court flatly rejected not only Forest's argument, but also its underlying reasoning based on the "statutory presumption of patent validity":

> Defendants complain that Mr. Johnston is not allowed to provide opinions that undermine the statutory presumption of patent validity - a presumption, they argue, that can be overturned only by clear and convincing evidence. *After a review of the challenged portions of Mr. Johnston's report, it is clear that his opinions do nothing of the sort*. (*See* Johnston Rep. ¶ 76-86; *87-109*; 112-20.) Again, Defendants are free to cross-examine Mr. Johnston and to argue that he gave insufficient weight to that hard-to-disprove presumption.

*In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 189 (S.D.N.Y. 2018) (McMahon, J.) (emphasis added) ("*Namenda V*").

Apparently dissatisfied with the Court's prior ruling and analysis – but unwilling even to acknowledge its existence or confront its reasoning – Forest simply ignores it.  Forest seeks to exclude Mr. Johnston's testimony on precisely the very same ground this Court previously rejected:

> Generalized evidence of the outcomes for brand and generic companies in all Hatch-Waxman litigations throughout the United States has no bearing on the merits of the specific patent case brought by Forest against Mylan and the other generic manufacturers . . . *What DPPs seek to do here is especially concerning, as it appears to be an attempt to make an end-run around the presumption of patent validity and the high evidentiary bar attendant in mounting an invalidity defense on the merits by clear and convincing evidence*.

Defs.' Br. at 1-2 (emphasis added). The Court properly rejected this argument the first time. *Namenda V*, 331 F. Supp. 3d at 189.

Given the foregoing history, Forest's MIL No. 2 should be denied as procedurally improper. First, it is an untimely motion for reconsideration. *Grand River Enterprises Six Nations, Ltd. v. King*, No. 02–cv–5068 (JFK), 2009 WL 1739893, at *1 (S.D.N.Y. June 16, 2009) ("A party's failure to make a motion for reconsideration in a timely manner is by itself a sufficient basis for denial of the motion."); S.D.N.Y.R. 6.3 ("Unless otherwise provided by the Court or by statute or rule . . . a notice of motion for reconsideration or reargument of a court order determining a motion shall be served within fourteen (14) days after the entry of the Court's determination of the original motion . . ."). Second, under the Third Amended Case Management Order, *Daubert* challenges to expert testimony were due on November 17, 2017. ECF No. 397 at 2. As reflected by the fact that Forest previously sought to exclude this same evidence at the *Daubert* stage, Forest's MIL No. 2 is a thinly-disguised *Daubert* motion rather than a "motion in limine" and should be rejected on that ground as well. *United States v. Teva Pharm. USA, Inc.*, Civ. No. 13-cv-3702, 2019 WL 1245656, at *12 (S.D.N.Y. Feb. 27, 2019) (McMahon, J.) ("As far as this court is concerned, the Parties have waived any *Daubert* arguments by not raising them at summary judgment. If I can consider an expert's [testimony] at summary judgment, a jury can consider it at trial."); *Hart v. BHH, LLC*, Civ. No. 15-cv-4804, 2019 WL 1494027, at *1 (S.D.N.Y. Apr. 4, 2019) ("But these are classic *Daubert* questions which could have been raised in the first *Daubert* motion. Accordingly, this Court construes Defendants' second motion *in limine* as an untimely *Daubert* motion in violation of this Court's scheduling order or as an untimely motion for reconsideration."). Third, even if Forest desired

late reconsideration, it should have at least acknowledged the Court's prior ruling and explained

any alleged shortcomings in that reasoning.  Forest did not even attempt that here.

      **B.**      **Generalized Statistical Evidence on Patent Cases Is Highly Relevant and Not Prejudicial to The Issues in This Reverse Payment Case for Two Reasons.**

Even if the Court addresses Forest's MIL No. 2 on the merits, the motion fails.  Forest is

demonstrably wrong when it argues that "DPPs cannot provide any explanation for why

evidence of brand and generic companies' performance in patent litigations, in general, has any

relevance" (Defs.' Br. at 4) in a reverse-payment case under *Actavis*.  In fact, not only can

Plaintiffs provide this explanation, Plaintiffs did provide this explanation in the *Daubert* briefing

relating to Mr. Johnston.  *See, e.g.*, ECF No. 654 at 16.  For the reasons that follow: (1) a

reasonable litigant's beliefs regarding the patent merits are highly relevant to both whether

Forest violated the antitrust laws and Plaintiffs' damages from that violation; and (2) statistical

studies on patent litigation outcomes available at the time of the challenged reverse-payment

settlement are highly probative of a reasonable litigant's beliefs regarding likelihood of success.

Tellingly absent from Forest's brief is ***any*** challenge to either of these two dispositive points.

      *1.*      *Forest's Reasoning Is Based on Its Continuing Misapprehension That This Is a Patent Infringement Case.*

Forest argues that historical statistical studies regarding other patent infringement cases

are "not relevant to whether a ***specific*** patent is infringed or should be upheld as valid."  Defs.'

Br. at 2 (emphasis in original).  If this was a patent infringement case and if the jury was being

asked to determine whether the '703 Patent "is infringed or should be upheld as invalid,"

Forest's argument might be cognizable.  But as this Court explained some time ago, "this is an

antitrust case, not a patent infringement case; the Court's concern with the technical issues of

patent infringement and validity is indirect."  *Namenda V*, 331 F. Supp. 3d at 187.  Forest clearly

understands this distinction: its proposed verdict form does not ask the jury to decide whether the

'703 Patent claims are "valid" or "infringed" as in a patent infringement case.  ECF No. 704-1 at

4 (Nos. 9-12).  The same is true of Plaintiffs' verdict form.  ECF No. 702-1.  Because the jury is

not being asked to reach a conclusion on whether the patent was in fact "infringed" or was in fact

"invalid," Forest's entire argument misses the mark.

Consistent with the parties' proposed verdict forms, and as this Court has noted, Mr.

Johnston is not opining that the patent claims are invalid or not infringed, but rather is offering an

opinion about a reasonable litigant's assessment of Mylan's likelihood of success:

> Mr. Johnston is not opining that the '703 is invalid, or that Mylan did not infringe
> the patent. Instead, he offers a "reasonable patent attorney's" assessment of the
> likelihood that Mylan would win its patent case – exactly the sort of assessment he
> would have offered his client during the nearly two decades when he served as
> Chief Patent Counsel of Hoffman-LaRoche.

*Namenda V*, 331 F. Supp. 3d at 187.  As described further below, the jury will be asked

questions whose answers turn on the beliefs of a reasonable litigant.  It therefore matters not

whether the statistical studies are probative evidence of whether the '703 Patent was in fact

infringed or valid; what matters is that the evidence is undisputed that the challenged statistical

studies are highly probative of the likelihood of success that a reasonable litigant in the Namenda

patent litigation would have perceived.

For the same reason, Forest's citations are inapposite.  Forest cites cases for the

unremarkable proposition that *in a patent infringement case*, when a jury is tasked with

*determining whether patent claims are actually valid or infringed*, the evidence relating to the

patent at issue controls the outcome on those particular issues.  Defs.' Br. at 2-3.  But again, this

is not a patent infringement case, and the jury is not being asked to decide whether the patent

claims are actually infringed and valid.

2.      *Forest's Beliefs Are Highly Relevant to This Antitrust Case.*

This Court has previously recognized that "***Forest's understanding*** of the strength of its

patent is highly relevant to this case." ECF No. 684 at 1 (emphasis added).  Notwithstanding that

Forest has asserted privilege, thereby blocking all discovery into its subjective beliefs, Forest's

beliefs are relevant for two distinct reasons.  First, regarding whether Forest's reverse-payment

settlement with Mylan violated the laws, the "relevant antitrust question" is why Forest agreed to

pay Mylan tens of millions of dollars.  *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013)

("Although the parties may have reasons to prefer settlements that include reverse payments, the

relevant antitrust question is: What are those reasons?").  If Forest paid Mylan to eliminate the

risk of losing the patent litigation, its reverse payment likely violated the antitrust laws.  *Id.* at

157 (holding that a reverse payment made "to prevent the risk of competition . . . constitutes the

relevant anticompetitive harm").  From the objective evidence, a jury can properly infer what

Forest, presumed to be a reasonable profit maximizing decision maker, believed.  Second,

Forest's beliefs are relevant to one of Plaintiffs' damages theory.  As this Court knows, one of

Plaintiffs' experts (*i.e.*, Professor Elhauge) offers opinions on what "the settlement entry date

would have been in a no-payment settlement."  *Namenda V*, 331 F. Supp. 3d at 172.  One of the

inputs to Professor Elhauge's economic analysis, if Forest and Mylan had decided to waive

privilege, would be the settling parties' *bona fide* beliefs regarding the strength or weakness of

the patent and Namenda patent litigation.  Declaration of Joseph Opper ("Opper Decl.") Ex. 11,

Elhauge Rpt, ¶¶ 17, 67-74.  Prof. Elhauge is entitled to rely on the objective view of a reasonable

litigant, particularly when the defendant's actual beliefs are withheld or when their bona fides are

called into question.  *Id.* ¶ 17.  *Cf. In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, Nos.

1:00-1898, MDL 1358 (SAS), M21-88, 2008 WL 1971538, at *11 (S.D.N.Y. May 7, 2008)

(crediting plaintiffs' expert's opinion that the parties would behave in "economically rational"

ways); *Dolphin Tours, Inc. v. Pacifico Creative Serv., Inc*., 773 F.2d 1506, 1511 (9th Cir. 1985) (plaintiffs "must presume the existence of rational economic behavior in the hypothetical free market"); *Murphy Tugboat Co. v. Crowley*, 658 F.2d 1256, 1262 (9th Cir. 1981) (a "reasonable jury could not . . . indulge in the assumption that a competitor would follow a course of behavior other than that which it believed would maximize its profits").

   3.  *Statistical Studies Are Highly Probative of a Reasonable Litigants' Beliefs*

  Against this legal backdrop, it is undisputed that reasonable litigants monitor and utilize statistical studies when evaluating likelihood of success in patent infringement cases.  As Mr. Johnston explained, "a reasonable and competent patent attorney faced with a request to evaluate the likelihood of success in a patent litigation would  . . . be aware of the statistical studies . . . and would have his or her own experience in patent litigations that in all likelihood would confirm the challenges for a patent owner prevailing in a patent infringement case."  Opper Decl. Ex. 12, Johnston Rpt, ¶ 111; *id*. at 28 n.49 (explaining why "a reasonable and competent patent attorney would [] ascribe some predictive value to those [statistical] studies"); *id*. ¶ 393 ("[A] reasonable and competent patent attorney asked to evaluate the parties' likelihood of success in the Namenda Litigation would start from an understanding position that it is difficult for a patent holder to overcome invalidity challenges and simultaneously prove infringement at trial. From statistical sources available in 2009–2010, the patent attorney would have understood that statistically, on average, a patent litigation defendant had approximately a 65 to 75% chance of success.")

  Like Mr. Johnston, Forest's expert Mr. McKelvie affirmatively relied on a statistical study in formulating his opinions in this case and in opining that Judge Sleet was likely to rule for Forest in the Namenda Patent Litigation.  Opper Decl. Ex. 13, McKelvie Rpt, ¶¶ 36, 38-39.

And Mr. McKelvie admitted at his deposition the importance of these types of studies for patent

attorneys:

> Q.    Do you agree that early in a patent infringement lawsuit, statistical studies
>       can be a helpful tool for patent attorneys in getting a general sense for
>       likelihood of success?
>
> A.    Yes.
>
> Q.    Over the course of your professional career, you have reviewed various
>       statistical studies addressing likelihood of success in patent litigation,
>       correct?
>
> A.    Yes.

Opper Decl. Ex. 14, McKelvie Oct. 18, 2017 Dep., at 69:20-70:7; Opper Decl. Ex. 13, McKelvie

Rpt, ¶ 40 (arguing that the statistics are "not that helpful" but acknowledging that "statistics on

the success of claims and defenses before judges, juries, and the court of appeals" to be "some

help in giving guidance to a litigant and trial lawyer").  The fact that both Forest's and Plaintiffs'

experts acknowledged the significance of statistical studies, recognized that reasonable litigants

rely upon them in assessing likelihood of success, and offered opinions based on different

statistical studies should dispose of this motion.  Forest's criticisms are better reserved for cross

examination.

Beyond merely rejecting Forest's *Daubert* challenge to Mr. Johnston's reliance on the

statistical studies (*supra*), the Court seemingly highlighted the reasonableness of Mr. Johnston's

reliance on the statistical studies as providing an "actual track record in real litigations":

> [Mr. Johnston] then examines other information that a reasonable patent counsel
> who was evaluating whether or not to settle a case would have taken into account.
> ***He explained data that showed the statistical likelihood that either a patentee or
> a challenger would win a Hatch-Waxman lawsuit – the actual track record in
> real litigations.*** He then evaluated, in the manner that a reasonable and competent
> patent attorney would, the information that was available to him about the merits
> of the Namenda litigation between Forest and Mylan. . . . In short, he does exactly

what he did time and again during his years as Chief Patent Attorney at Hoffman-LaRoche.

*Namenda V*, 331 F. Supp. 3d at 186 (emphasis added).  Notably, Forest has not identified any reason why reasonable litigants would not consider statistical studies on outcomes in patent cases when settling, particularly given that those studies reflect the historical averages for what happens when they do not settle.

This Court is not the only Court to recognize the propriety of this type of statistical evidence in *Actavis*-type cases. In *In re Androgel Antitrust Litigation (No. II)*, the plaintiffs offered the expert testimony of a patent attorney, Mr. Jack Goldstein, regarding "how a reasonable and competent patent attorney would have advised litigants in [the settling parties'] positions" as to, *inter alia*, "the likelihood of success in the [patent] litigation."  *In re Androgel Antitrust Lit. (No. II),* Civ. No. 1:09-cv-955-TWT, 2018 WL 2984873, at \*5 (N.D. Ga. June 14, 2018).  The brand name drug company moved to exclude Mr. Goldstein's analysis, which was predicated in part on statistical analyses regarding likelihood of success.  *Id*. at \*6.

The *In re Androgel* court rejected that challenge:

> ***Goldstein began his analysis by using two studies available at the time of the settlement to assess what the average outcomes were in patent cases involving a generic defendant.*** Using these studies, it is Goldstein's opinion that on average a brand manufacturer plaintiff would have about a 25-30% chance of winning a Hatch-Waxman patent infringement case. ***Goldstein then examined the merits of the underlying patent litigation in this case to determine whether [the brand company's] position was stronger or weaker than the average Hatch-Waxman plaintiff. Goldstein found that it was weaker than the average, although not by a lot.*** Goldstein estimated that a reasonable and competent patent attorney would have discounted Solvay's chances of success by about 10%, meaning that it would have had between a 15-20% chance of succeeding in the underlying litigation. Goldstein clearly has a methodology, even if the Defendants believe it to be a weak one. Similarly, Goldstein's opinions on the merits, cost, and timing of the litigation are reliable enough to be put to a jury. ***Although the Defendants argue that his views on the law are unreliable because they are incorrect, that is something on which reasonable and competent patent attorneys can disagree.***

*Id*. at \*6-7 (emphasis added).  In addition to a full-blown analysis of the merits of several of

Mylan's patent defenses, Mr. Johnston also provides the same type of analysis approved in

*Androgel* as a cross-check.  Specifically, Mr. Johnston concluded that "viewed conservatively,

the statistics show that, on average, a patent litigation defendant had at least a 60% chance of

success" and that "it is [his] opinion that Mylan's case was stronger than the average accused

infringer's case" so that "speaking conservatively Mylan's likelihood of success was greater than

60%." Opper Decl. Ex. 12, Johnston Report, ¶ 393; *see also id*. ¶ 16a.

Forest's Brief fails to offer any reason why – in the context of this *antitrust* case –

historical patentee win rates are not highly relevant to a reasonable litigant's assessment of

likelihood of success.  Indeed, as the *Androgel* court recognized, one acceptable approach for

estimating a reasonable litigant's expectation of success is to <u>begin</u> with historical win rates as a

baseline, and <u>then</u> adjust likelihood of success upward or downward based on the strength of the

case at hand relative to prior cases.  *In re Androgel Antitrust Lit. (No. II),* 2018 WL 2984873, at

\*6 (finding a patent litigation expert's analysis "reliable" where he "began his analysis by using

two studies available at the time of the settlement to assess what the average outcomes were in

patent cases" and "then examined the merits of the underlying patent litigation in this case to

determine whether [the brand company's] position was stronger or weaker than the average

Hatch-Waxman plaintiff").

Although Forest argues that evidence of the statistical studies is prejudicial, it fails to

explain why such evidence is unfairly prejudicial in an *antitrust case*, as contrasted from a *patent*

*infringement case*.  The distinction is important.  Given that the beliefs of a reasonable litigant

are a central issue in this antitrust case and it is undisputed that these statistical studies are highly

probative of that issue, it would be unfairly prejudicial to Plaintiffs to exclude evidence of the

studies.  Reasonable litigants (and undoubtedly Forest) know that patent owners lose patent cases far more often than they win them.  Excluding the statistical studies would enable the jury to labor under the misimpression that patent owners believe they are on average favorites to win, when in fact all sophisticated patent owners know the reverse is true.

Even if Forest had identified some purported "unfair prejudice" from the statistical studies in the context of this *antitrust case* – and Forest has not – it could not possibly "substantially outweigh[]" the indisputably highly probative value of the statistical studies in establishing the beliefs of a reasonable litigant regarding likelihood of success as required for exclusion under Rule 403.  Fed. R. Evid. 403.  This is particularly the case in the Second Circuit, which maximizes the probative value and minimizes the prejudicial value in applying Rule 403. *United States v. Monsalvatge*, 850 F.3d 483, 494 (2d Cir.), *cert. denied*, 138 S. Ct. 280, (2017) ("[I]n reviewing a district court's Rule 403 ruling, we generally maximiz[e] [the evidence's] probative value and minimiz[e] its prejudicial value.") (internal quotations omitted).

## III.   CONCLUSION

For the foregoing reasons, Plaintiffs request that this Court deny Forest's motion *in limine* No. 2.

Dated: June 14, 2019                                    Respectfully Submitted:

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## CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, I electronically filed the above by CM/ECF system.


Respectfully submitted,

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